EXHIBIT D

Complication and Reoperation Rates After Apical Vaginal Prolapse Surgical Repair

A Systematic Review

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OBJECTIVE: To compare postoperative complication and reoperation rates for surgical procedures correcting apical vaginal prolapse.

DATA SOURCES: Eligible studies were selected through an electronic literature search covering January 1985 to January 2008 using PubMed, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews and Effects.

METHODS OF STUDY SELECTION: Only clinical trials and observational studies addressing apical prolapse repair and recurrence or complication rates were included. The search was restricted to original articles published in English with 50 or more participants and a follow-up period of 3 months or longer. Oral platform and poster presentations from the American Urogynecological Society, the Society for Gynecologic Surgeons, the International Urogynecological Association, and the International Continence Society from January 2005 to December 2007 were hand searched to determine whether they were eligible for inclusion.

TABULATION, INTEGRATION, AND RESULTS: Procedures were separated into three groups: traditional vaginal surgery, sacral colpopexy, and vaginal mesh kits. Complications were classified using the Dindo grading system. Weighted averages were calculated for each Dindo grade, complication, and reoperation. Dindo grade IIIa (433/3,425 women) and IIIb (245/3,425) rates were highest in the mesh kit group owing to higher rates of mesh erosion (198/3,425) and fistulae (8/3,425). Reoperation rates for prolapse recurrence were highest in the traditional vaginal surgery group (308/7,827). The total reoperation rate was greatest in the mesh kit group (291/3, 425, 8.5%).

CONCLUSION: The rate of complications requiring reoperation and the total reoperation rate was highest for vaginal mesh kits despite a lower reoperation rate for prolapse recurrence and shorter overall follow-up.
(Obstet Gynecol 2009;113:367–73)

Pelvic organ prolapse often involves a combination of support defects involving the anterior, posterior, and apical vaginal segments. There is growing recognition that adequate support for the vaginal apex is an essential component of a durable surgical repair for women with advanced prolapse.[1–3] The Surgery for Pelvic Organ Prolapse Committee of the 3rd International Consultation on Incontinence noted that "the apex is the keystone of pelvic organ support . . . the best surgical correction of the anterior and posterior walls is doomed to failure unless the apex is adequately supported."[1] Restoring the anatomy of the vaginal apex by apical suspension can be achieved by several techniques, with the "gold standard" being sacral colpopexy.[4] Traditional vaginal approaches include sacrospinous ligament fixation, uterosacral ligament suspension, iliococcygeus muscle suspension, and McCall's culdoplasty. More recently, commercially available vaginal mesh kits that use trocars to place permanent mesh transvaginally have gained in popularity.[5] However, none of these techniques is without risks for complications or prolapse recurrence.

Data are lacking that compare complication and recurrence rates of traditional procedures with vaginal mesh kits. We hypothesize the following: 1) sacral

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Presented at the American Urogynecologic Society 29th Annual Scientific Meeting, September 4–6, 2008, Chicago, Illinois.

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Financial Disclosure
The authors did not report any potential conflicts of interest.

ISSN: 0029-7844/09

colpopexy and traditional vaginal surgeries have fewer operative complications compared with vaginal mesh kits, and 2) recurrent prolapse rates are higher in the traditional vaginal surgery group compared with the vaginal mesh kit group. The objective of this meta-analysis is to compare complication and prolapse recurrence rates after sacral colpopexy, traditional vaginal surgeries, and vaginal mesh kits that aim to repair prolapse of the vaginal apex.

SOURCES

Eligible studies were selected through an electronic literature search from January 1985 to January 2008 using PubMed, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews and Effects, and the ACP Journal Club. The search strategy was formulated and conducted with the assistance of a professional medical research librarian. Search terms included the following keywords and phrases: "vaginal prolapse and surgery," "uterine prolapse and (complications or prevention) and (control or surgery or therapy)," "uterosacral," "sacrospinous," "sacrospinous ligament," "sacrocolpopexy," "sacral colpopexy," "colpopexy," "sacropexy," "sacrouteropexy," "iliococcygeus," "prolift," "apogee," "avaulta," "vaginal vault and prolapse," "apical vaginal and prolapse," "vaginal mesh," and "vaginal mesh and prolapse." Keywords appeared in the title, abstract, or both.

STUDY SELECTION

The search was restricted further to original articles published in English that included 50 or more participants and had a follow-up period of 3 months or longer. Only clinical trials and observational studies addressing apical prolapse repair and associated recurrence or complication rates were included. Case reports were excluded. If data were published in multiple studies, the study with the longest follow-up period was selected for inclusion. Oral platform and poster presentations from the American Urogynecological Society, the Society for Gynecologic Surgeons, the International Urogynecological Association, and the International Continence Society from January 2005 to December 2007 were hand searched to determine whether they were eligible for inclusion. Reference lists from review articles and sentinel trials were searched for additional studies.

Two independent reviewers assessed eligibility and abstracted data from each study. In cases of discordance between reviewers regarding study eligibility, differences were discussed until a consensus was reached. If unable to reach a consensus, a third reviewer intervened to make a final decision. Data were abstracted using a standardized form. Meta-Analysis of Observational Studies in Epidemiology guidelines were followed.[6]

The studies were separated into three groups: 1) traditional vaginal procedures, 2) sacral colpopexy, and 3) vaginal mesh kits. Traditional procedures included uterosacral ligament suspension, sacrospinous ligament suspension, iliococcygeus fascial suspension, and McCall's culdoplasty. The sacral colpopexy group included standard sacral colpopexies as well as sacrocervicopexies and sacrohysteropexies by laparoscopy or laparotomy. The vaginal mesh kit group included Apogee (American Medical Systems, Inc., Minnetonka, MN), Posterior Gynecare Prolift System and Total Gynecare Prolift System (Ethicon Women's Health and Urology, Somerville, NJ), Total Vaginal Mesh and Posterior Intravaginal Slingplasty (Tyco Healthcare, United States Surgical, Norwalk, CT), and other miscellaneous transvaginal approaches to support the apex involving permanent mesh. For Total Prolift, we attempted to distinguish between the anterior and apical (includes Posterior Prolift) outcomes. Studies were excluded if it was difficult to make this distinction clearly. In the case of a study with multiple treatment arms, each arm was classified into one of the corresponding groups outlined above.

Complications were classified using the Dindo grading guidelines,[7] which is a valid surgical-complication grading system based on the invasiveness of an intervention used to treat a complication (Table 1). For complications that were unable to be classified clearly using this system, a Dindo grade was assigned before abstraction to prevent discrepancies between reviewers. Because hemorrhage rarely was defined by authors, any reported case of "hemorrhage" or "hematoma" was classified as a "hemorrhage" for the purposes of this study. Pulmonary complications included any case of pneumonia, acute respiratory distress syndrome, or pulmonary edema. Cardiac complications included myocardial infarction, congestive heart failure, and arrhythmias. Injuries to the bowel, bladder, or ureters were classified as "visceral injuries." Complications excluded from the meta-analysis included bladder symptoms unrelated to visceral injury, fecal incontinence, complications unrelated to the apical prolapse surgery such as anesthesia complications (eg, spinal headache), and complications that unequivocally resulted from concomitant procedures. Treatment was not always specified for patients with mesh erosion. Therefore, we assumed

Table 1. Dindo Grading

Dindo Grade	Criteria
I*	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or radiological interventions Includes wound infections opened at the bedside Includes drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy
II	Requiring pharmacological treatment with drugs other than those allowed for grade I complications Includes blood transfusions and total parenteral nutrition
IIIa	Requiring surgical, endoscopic, or radiological intervention not under general anesthesia
IIIb	Requiring surgical, endoscopic, or radiological intervention under general anesthesia
IVa	Life-threatening complication requiring intensive care unit management–single organ dysfunction (includes dialysis)
IVb	Life-threatening complication requiring intensive care unit management–multiorgan dysfunction
V	Death

Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205–13. Copyright 2004 Lippincott Williams & Wilkins.

* Hematoma, pain, dyspareunia, and fever were assigned Dindo grade I if intervention was not specified.

that 50% of participants were treated medically (Dindo II) and the remaining 50% were treated surgically under anesthesia (Dindo IIIb). If erosion management was treated in the office setting, 50% of participants were assumed to be treated medically (Dindo II) and the remaining participants were treated surgically without general anesthesia (Dindo IIIa). Sensitivity analyses were performed, varying these rates between 25% and 75% to evaluate the effect of our a priori assumptions. Because multiple prolapse grading systems and varying definitions of prolapse recurrence were used throughout the studies, we could not compare anatomic prolapse recurrence between the surgical groups. However, we were able to collect reoperations for prolapse recurrence. Weighted averages and confidence intervals were calculated for Dindo grades, complications, reoperations for prolapse recurrence, and total reoperations (complications treated surgically under general anesthesia [Dindo IIIb] and surgery for prolapse recurrence). Because the focus of this report is on complications and there were few clinical trials comparing the three approaches, no other formal meta-analytic techniques were used beyond the weighted averages described above. Statistics were calculated using JMP 7.0 (SAS Institute, Cary, NC).

RESULTS

A total of 249 peer-reviewed articles and 19 conference abstracts met the initial search criteria. Of those, 162 articles were excluded by reviewers because they did not meet the predefined inclusion criteria. A total of 106 studies were included in the meta-analysis, of which 19 were conference abstracts. The characteristics of included and excluded studies are in the Appendix, available online at http://links.lww.com/A646. Table 2 summarizes the weighted averages and confidence intervals for complications, Dindo grades, prolapse reoperation rates, and total reoperation rates.

The traditional vaginal surgery group included 7,827 patients from 48 studies and had the longest follow-up period of 32.6±19.8 months. Of the 48 studies, 35 addressed sacrospinous ligament suspension, eight uterosacral ligament suspension, three iliococcygeus suspension, and two McCall's culdoplasty. The mean total complication rate for this group was 15.3% (range 0–52.8). The majority of complications in this group required pharmacologic intervention (6.9%) or did not require any intervention (6.2%). The most common complications included urinary tract infection (3.5%), hemorrhage or hematoma (2.8%), and dyspareunia (1.5%). Four cases of cerebral ischemia were reported in this group. However, it is unclear whether this complication was due to a preexisting medical condition or was a result of the surgery itself. The reoperation rate for prolapse recurrence was highest (3.9%, range 0–29.1) in this group compared with the other two surgical groups. However, the total reoperation rate, including reoperations for complications as well as prolapse, was the lowest (5.8%, range 0–29.2).

The sacral colpopexy group included 5,639 patients from 52 studies, with mean follow-up of 26.5±20.1 months. Thirty-nine studies addressed sacral colpopexy by laparotomy, 10 laparoscopic sacral colpopexy, and three sacrohysteropexy. This group had the highest mean total complication rate of 17.1% (range 0–52.2). Similar to the traditional vaginal surgery group, the majority of complications were managed with pharmacologic intervention (5.8%) or no intervention (5.5%). Pain (2.3%), mesh erosion (2.2%), visceral injury (1.7%), and wound complica-

Table 2. Weighted Averages and Confidence Intervals of Complications, Dindo Grades, Prolapse Reoperation Rates, and Total Reoperation Rates

	Traditional Vaginal Repair*	Sacral Colpopexy	Mesh Kits
Number of studies†	48	52	24
Number of patients	7,827	5,639	3,425
Mean follow-up (mo±SD)	32.6±19.8	26.5±20.1	17.1±13.8
Dindo grade I	6.2 (5.7–6.7), 0–52.8	5.5 (4.9–6.1), 0–52.2	3.9 (3.3–4.6), 0–23.1
Dindo grade II	6.9 (6.4–7.6), 0–34.7	5.8 (5.2–6.4), 0–25.9	2.2 (1.7–2.7), 0–14.8
Dindo grade IIIa	0.2 (0.1–0.4), 0–2.1	1.0 (0.7–1.2), 0–8.3	1.3 (0.9–1.6), 0–12.7
Dindo grade IIIb	1.9 (1.7–2.3), 0–12.0	4.8 (4.2–5.4), 0–28.2	7.2 (6.3–8.0), 0–21.2
Dindo grade IVa, b	0.1 (0–0.1), 0–1.0	0.0 (0–0.07), 0.0	0.0 (0–0.1), 0.0
Dindo grade V	0.1 (0–0.1), 0–0.7	0.0 (0–0.07), 0.0	0.0 (0–0.1), 0.0
Mesh erosion or infection	0.5 (0.3–0.6), 0–20.0	2.2 (1.8–2.6), 0–28.2	5.8 (5–6.6), 0–21.2
Visceral injury‡	1.0 (0.8–1.3), 0–5.9	1.7 (1.3–2.0), 0–10.7	1.1 (0.7–1.4), 0–5.0
Cystotomy	0.4 (0.2–0.5), 0–5.9	1.0 (0.8–1.3), 0–10.7	0.7 (0.4–1.0), 0–4.3
Ureteral injury	0.3 (0.2–0.4), 0–3.5	0.2 (0.1–0.3), 0–1.6	0.1 (0–0.1), 0–1.0
Bowel injury	0.4 (0.3–0.5), 0–3.1	0.5 (0.3–0.7), 0–3.6	0.3 (0.1–0.5), 0–5.0
Pain§	1.6 (1.3–1.9), 0–38.9	2.3 (1.9–2.6), 0–25.0	2.5 (2.0–3.0), 0–23.1
Buttock pain	1.0 (0.8–1.3), 0–52.8	0.0 (0–0.07), 0–5.9	0.4 (0.2–0.7), 0–8.3
Dyspareunia	1.5 (1.2–1.8), 0–38.9	1.5 (1.1–1.8), 0–22.8	2.2 (1.7–2.7), 0–23.1
Fistula	0.1 (0–0.1), 0–1.5	0.0 (0–0.07), 0–0.8	0.2 (0.1–0.4), 0–4.2
Hemorrhage or hematoma	2.8 (2.5–3.3), 0–19.6	1.6 (1.3–1.9), 0–11.5	1.1 (0.7–1.4), 0–3.0
Wound complications‖	0.5 (0.4–0.7), 0–10.8	1.5 (1.2–1.8), 0–16.8	0.2 (0–0.3), 0–7.5
Pelvic abscess	0.2 (0.1–0.3), 0–1.4	0.1 (0–0.2), 0–3.2	0.1 (0–0.2), 0–3.3
Lower extremity neuropathy	0.4 (0.3–0.6), 0–7.5	0.2 (0.1–0.3), 0–0.5	0.0 (0–0.1), 0.0
Urinary tract infection	3.5 (3.1–3.9), 0–34.8	2.1 (1.8–2.5), 0–25.9	0.8 (0.5–1.2), 0–14.8
Pulmonary embolism or deep vein thrombosis	0.1 (0.1–0.2), 0–2.2	0.3 (0.1–0.4), 0–3.2	0.0 (0–0.1), 0–1.4
Pulmonary complications	0.5 (0.4–0.7), 0–14.0	0.1 (0.1–0.4), 0–0.7	0.0 (0–0.1), 0.0
Cardiac complications	0.2 (0.1–0.3), 0–2.2	0.2 (0.1–0.3), 0–3.3	0.0 (0–0.1), 0.0
Total complication rate	15.3 (14.7–16.3), 0–52.8	17.1 (16.1–18.1), 0–52.2	14.5 (13.3–15.7), 0–23.1
Reoperation for prolapse recurrence	3.9 (3.5–4.4), 0–29.1	2.3 (1.9–2.7), 0–31.3	1.3 (1.0–1.7), 0–16.0
Total reoperation rate¶	5.8 (5.3–6.3), 0–29.2	7.1 (6.4–7.8), 0–26.2	8.5 (7.6–9.4), 0–30.0

SD, standard deviation.
Data are % (95% confidence interval), range unless otherwise specified.
* Includes sacrospinous ligament suspension, uterosacral ligament suspension, iliococcygeus muscle suspension, and McCall's culdoplasty.
† Ten studies included multiple cohorts from different procedure groups.
‡ Includes cystotomy, ureteral injury, and bowel injury.
§ Includes buttock pain, dyspareunia, and unspecified pain.
‖ Includes wound infections, vaginal cuff infections, and vaginal and abdominal wound dehiscences.
¶ Includes reoperations for complications (Dindo IIIb) and prolapse recurrence.

tions (1.5%) were the most common complications. There were 31 cases of dehiscence in the sacral colpopexy group compared with seven and four in the traditional vaginal surgery and mesh kit groups, respectively. Pulmonary emboli and deep vein thrombosis cases were reported more commonly after sacral colpopexy.

The vaginal mesh kit group included 3,425 patients from 24 studies, with a mean follow-up of 17.1±13.8 months. The mean total complication rate for this group was 14.5% (range 0–23.1). In contrast to the traditional vaginal surgery and sacral colpopexy groups, the majority of complications in this group required surgical intervention under general anesthesia (Dindo grade IIIb). Mesh erosion or infection was the most common complication (5.8%). Twenty-five studies from all three groups, including four of the 24 studies in the vaginal mesh kit group, did not report how they managed these erosions, and it was assumed that 50% were managed in the operating room (Dindo IIIb).[8–32] Sensitivity analyses revealed no substantial effect on rates of reoperation for complications by varying this assumed proportion between 25% and 75%. Although fistulae were reported rarely (0.2%, range 0–4.2), the rate was highest for this group. Although pain-related complications were common in the sacral colpopexy group, dyspareunia rates were highest in the mesh kit group (2.2%, range 0–23.1). The reoperation rate for recurrent prolapse was lowest (1.3%, range 0–16.0) in the vaginal mesh kit group, although follow-up was shortest in this group. Additionally, the total reoperation rate was the highest

(8.5%, range 0–30.0) because of a higher rate of reoperations for complications such as mesh erosion.

CONCLUSION

The findings of this meta-analysis demonstrate that total complication rates appear to be similar for traditional vaginal surgeries, sacral colpopexies, and vaginal mesh kits for the treatment of apical prolapse. However, despite having the shortest follow-up period out of the three groups, the reoperation rate for complications and total reoperation rate (including complications and prolapse recurrences) was highest in the vaginal mesh kit group. Most of these reoperations are necessitated by fistulae and mesh erosions. These complications are difficult to prevent, affect quality of life, and often are not managed medically. Although visceral injury and mesh erosion also led to reoperations in the sacral colpopexy and traditional vaginal surgery groups, the majority of all complications in these groups was managed pharmacologically. An additional key finding was that, despite the longer follow-up and greater number of participants, there was a lower total complication rate in the traditional vaginal surgery group compared with sacral colpopexy. The relatively higher rate of visceral injuries and wound complications in the sacral colpopexy group is likely attributed to the abdominal approach.

Our results are consistent with most past reviews of traditional vaginal surgeries and sacral colpopexy, and the few inconsistencies can be explained easily. Nygaard et al report the reoperation rate for prolapse recurrence after sacral colpopexy to be 4.4%, compared with our reoperation rate of 2.2%. Our meta-analysis included studies after 2004 and excluded more than 20 studies that were included in the review by Nygaard et al owing to sample size limitations or follow-up period. Mesh erosion rates were also higher (3.4%) in the study by Nygaard et al, likely for similar reasons.[33] In addition, the use of improved mesh quality such as synthetic monofilament materials may have decreased overall erosion rates.[34] Our results indicate a prolapse recurrence reoperation rate of 3.9% after traditional surgeries, with the majority of initial surgeries being sacrospinous ligament suspensions. Past reports have ranged up to 13%; the largest study of 243 patients reported a rate of 4.5%,[35] comparable with our current results. Similarly, reoperation rates for recurrence after uterosacral ligament suspension have ranged from 3% to 6.5% in large studies.[36,37] Olsen et al[38] report a reoperation rate for prolapse or incontinence repair of 29.2%. However, the study included reoperations after primary surgery on the apical, anterior, and posterior compartments in addition to incontinence repairs.

The Dindo grading system[7] is a valid method to grade complications based on the invasiveness of the intervention. Although the use of this grading system is a strength of our study, it is not a perfect system because it is designed to be applied to different surgical procedures. Because the specifics of the intervention were not always stated by the authors, assumptions were made. These limitations were evident for complications requiring nonsurgical management (eg, lower extremity neuropathy and dyspareunia) where there was uncertainty regarding whether pharmacologic management was used (Dindo II) or not (Dindo I). This also was seen in cases of hemorrhage, where transfusion (Dindo II) or observation (Dindo I) usually was not indicated. To make comparisons between surgical procedures in the future, surgical trials should make attempts to list minor and severe complications and provide as much detail regarding any interventions needed to manage those complications.

Efforts were taken in this review to avoid reporting bias and publication bias by excluding studies that reported on only a specific complication rather than all complications. In addition, recent conference abstracts, most of which studied mesh kits, were included to further reduce a negative publication bias. We recognize that the use of abstracts may not have provided sufficient details of the study owing to word limitations. Furthermore, only the most morbid or most prevalent complications are mentioned in the abstract, with the remainder of the complications stated in the article. We elected to exclude studies with less than 3 months of follow-up because most prolapse reoperations would not have been diagnosed within this short time period.

There are several reasons that comparisons among the three surgical approaches should be interpreted with caution. First, very few randomized trials comparing these techniques are currently available. Of the 105 studies included in our analysis, only 4% represent clinical trials. Most of the studies included are retrospective case series of a single procedure without a comparison group. As such, the type of analysis we could perform is limited, and formal meta-analytic techniques could not be performed. Second, studies addressing traditional vaginal procedures and sacral colpopexy were likely better quality studies compared with studies on vaginal mesh kits, given the longer follow-up periods and larger sample sizes. The lowest rate of prolapse recurrence seen in the mesh kit group may be because the addition of

mesh improves objective anatomic cure, but it also may be a reflection of the follow-up period of 17.1 months, which is approximately half the follow-up period of the traditional procedures group. Future trials with longer follow-up ultimately will determine whether recurrence rates increase or remain unchanged. Third, given the variability of follow-up times among studies, time-to-event analyses would be ideal. However, because the timing of adverse events and reoperations often was not reported, these could not be performed. Finally, the number of patients enrolled and the number of patients lost to follow-up was not always indicated in every study.

An additional limitation was that most apical prolapse surgeries were performed with concomitant procedures. Procedures such as midurethral slings that use mesh can contribute to complications that may be difficult to discern from complications due to solely apical procedures. For example, there was a 0.5% mesh erosion rate in the traditional surgery group, although none of the procedures in this group involved the use of mesh.[39,40] Finally, because studies were grouped by the three approaches (traditional, sacral colpopexy, and mesh kits), comparisons cannot be made among procedures within a group. For example, conclusions cannot be drawn regarding which vaginal mesh device had the highest morbidity or which mesh material in the sacral colpopexy group led to the most mesh erosions.

In summary, there are no clinical trials or other comparative studies to date that compare these three main approaches to repairing the apical compartment in women undergoing surgery for pelvic organ prolapse. In this meta-analysis, we attempted to summarize the available observational studies to provide some guidelines on the relative complication and reoperation rates of these approaches. Sacral colpopexy is considered by some the gold standard apical suspension procedure.[4] In support of this, sacral colpopexy had a relatively low rate of reoperation for prolapse recurrence. However, this was at the expense of a high complication rate. Traditional vaginal procedures, in contrast, had a higher rate of reoperation for prolapse recurrence but fewer complications that required surgical intervention. Most importantly, our results suggest that, despite the lowest reoperation rate for prolapse recurrence, vaginal mesh kits have the highest rate of complications that require surgical intervention, which, on balance, results in the highest rate of total reoperation after apical suspension for pelvic organ prolapse. This raises the concern that the risks of these newer procedures may be greater than their benefits. One can speculate that more recurrences and complications may be diagnosed with time, given the relatively shorter mean follow-up period in the mesh kit group. On the other hand, this may reflect the "learning curve" of this recently adopted new technology. More long-term studies on vaginal mesh kits and clinical trials that directly compare these surgical techniques are needed to support these findings definitively.

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